

## **REMARKS**

### **I. Support for the Amendments**

Claims 1 and 3-11 were previously in the application. Claims 1 and 3 have been amended, claim 12 has been added, and claims 4-11 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application. Claims 1, 3, and 12 are currently in the application. Claims 1 and 3 are the independent claims.

Support for amended claims 1 and 3 and for new claim 12 can be found in the original specification and claims.

Additional support for amended claims 1 and 3 and for new claim 12 can be found, e.g., from page 3, line 14, to page 7, line 7; from page 7, line 19, to page 67, line 3; on page 7, lines 19-21; on page 10, lines 11-21; from page 17, line 31, to page 19, line 3; from page 19, line 27, to page 23, line 12; from page 24, line 1, to page 36, line 4; from page 36, line 5, to page 39, line 21; from page 40, line 1, to page 42, line 7; from page 46, line 14, to page 53, line 2; from page 56, line 17, to page 58, line 4; from page 58, line 26, to page 60, line 34; on page 71; and in the Examples.

### **II. Status of the Claims**

Claims 1-3 were originally in the application, with claims 1 and 3 being the independent claims. Claims 1-3 were subject to an Election/Restriction Requirement, and claims 1 and 3 (Group I) were elected with traverse.

Claims 1 and 3-11 were previously in the application. Claims 1 and 3 have been amended, claim 12 has been added, and claims 4-11 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application. Claims 1, 3, and 12 are currently in the application. Claims 1 and 3 are the independent claims.

### **III. The Translation of the Priority Application**

Applicants thank the Examiner for acknowledging the priority claim based on Japanese Application 236597/1999, filed in Japan on 24 August 1999. The Office Action states that the certified copy was filed in PCT/JP00/05639 on 23 August 2000.

The Office Action further states:

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action. [P. 2; par. 4.]

Applicants submit herewith the translation of the priority document (Japanese Patent Application No. 1999-236597, along with the verification of the translation.

### **IV. The Objection to the Drawing**

Applicants thank the Examiner for withdrawing the objection to the drawing.

### **V. The Objections to the Specification**

Applicants thank the Examiner for withdrawing the objections to the specification.

**VI. The Rejection of Claims 1 and 3-11 under 35 U.S.C. §112, Second Paragraph, is Traversed in Part, Accommodated in Part, and Rendered Moot in Part**

While the Examiner withdrew some of the rejections of claims 1 and 3, the Examiner has rejected claims 1 and 3-11 under 35 U.S.C. §112, second paragraph (pp. 4-6).

The Patent Office alleges:

16. Claim 1 and 3 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reasons set forth at page 5 (¶15) in the previous Office Action (mailed 27 January 2005). As stated at page 5 of the previous Office Action, since it is unclear how much the structure of the candidate compound can deviate from a referenced structure and still have "a common structure", the metes and bounds of the claim cannot be determined.

17. At pages 12-13 of the response (filed 27 April 2005), Applicants refer the Examiner to the discussion of such as pages 34-35 of the Specification. Applicants argue that those skilled in the art would be able to recognize an appropriate extent of deviation from a common structure from a referenced structure based on the description at pages 34-35 and related descriptions in the present specification.

18. Applicant's arguments have been fully considered but they are not persuasive for the following reasons. The discussion of "common structures" at pages 34-35 is noted but vague, fails to breathe life and meaning into the term, is exemplary rather than limiting, and thus is insufficient to render the claims definite. Furthermore, it is inappropriate to read limitations in the specification, much less the general knowledge of one of ordinary skill in the art, into the claims. The claims must independently define the invention for which patent protection is sought. It is noted that the discussion of "R-X-NH<sub>3</sub> structure at C-terminus" as an example of a common structure refers to when a specific receptor, namely FM-3, is the orphan receptor protein, and the instant claims are not limited in scope to the FM-3 receptor.

19. Claims 1 and 3 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Part (ii) of each claim, "extracting a common structure", does not set forth any steps involved in the method/process, therefore it is unclear what method/process is encompassed by the claims.

20. Claim 1 recites the limitation "test compound (b)" in part (iii) line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

21. Claims 1 and 3 are rejected as being indefinite because it is unclear what is being compared. For example, claim 1 recites three different groups of compounds (test compound A, ligand candidate compounds, and test compound B), and it is unclear what compounds are encompassed by the limitation "if there is an increase

in the amount of specific binding as compared to non-specific binding", as recited in part (iii) lines 9-10 of the claim. Likewise, since claim 3 recites two different groups of compounds (test compound A and ligand candidate compounds), it is unclear what is encompassed by the limitation "which shows an increase in the amount of specific binding to said orphan receptor as compared to non-specific binding", as recited in part (iv) of the claim.

22. Claims 4 and 8 are rejected as being indefinite for reciting the phrase "a common three-dimensional structure". Since neither the art nor the specification provides an unambiguous definition of the phrase "a common three-dimensional structure", the claims are indefinite.

23. Claims 5-6 and 9-10 are rejected as being indefinite because it is unclear if the terms "protein" and "peptide" are intended to refer to the same or different compounds. [Pp. 4-6; pars. 16-23.]

Applicants disagree, but respectfully submit that the amendments to claims 1 and 3 address these points.

Claims 4-6 and 8-10 have been canceled, and the rejections of these claims are rendered moot. Aside from dependency on rejected claims, there are no specific rejections of claims 7 and 11 with respect to 35 U.S.C. §112, second paragraph, but the claims have also been canceled, and the rejections of these claims are likewise rendered moot.

With respect to paragraphs 16-19, Applicants have restricted the common structure to R-X-NH<sub>3</sub> at the C-terminus (see, e.g., p. 35). Applicants respectfully refer the Examiner to the discussion, e.g., at pages 34-35 of the specification. Applicants submit that "a common structure" refers to a homology and/or a similarity in a steric structure between or among compounds, as would have been understood by one of ordinary skill in the art at the time when the application was filed. Moreover, those skilled in the art would be able to recognize an appropriate extent of deviation from a common structure from a referenced structure based on the description at pages 34-35 and related descriptions in the present specification. In the present screening method, a candidate compound is firstly selected based on a common structure, and then the selected candidate compound is further screened based on an amount of specific binding. If the common structure is deviated from a

referenced structure to a great extent, then the next screening step based on the amount of the specific binding would become laborious, and if the common structure is deviated from a reference structure to a small extent, then the next screening step based on the amount of the specific binding would be relatively easy, because the structure of a compound is normally correlated to its activity. Therefore, those skilled in the art would be able to know or predict which structures would have a reasonable expectation of success and therefore determine an appropriate extent of the deviation of a common structure from a referenced structure depending on their purpose and/or conditions.

With respect to paragraph 20, Applicants have restricted test compound (b) to a “peptide having a structure of R-X-NH<sub>3</sub> at its C-terminus.”

With respect to paragraph 21, Applicants have amended claims 1 and 3 to read “if there is specific binding,” rather than “if there is an increase in the amount of specific binding as compared to non-specific binding.”

In addition, the compound has been limited to a peptide.

Applicants respectfully submit that the present amendments to claims 1 and 3 accommodate the Examiner’s rejection of these claims under 35 U.S.C. §112, second paragraph, thereby placing these claims in condition for allowance.

**VII. The Rejection of Claims 1 and 3-11 under 35 U.S.C. §112, First Paragraph, is Traversed in Part, Accommodated in Part, and Rendered Moot in Part**

The Examiner has rejected claims 1 and 3-11 under 35 U.S.C. §112, first paragraph (pp. 6-7), alleging failure to comply with the written description requirement and introduction of new matter. Applicants respectfully disagree.

The Patent Office alleges:

Claims 1 and 3 recite "*extracting* a common structure", claims 4 and 8 recite a "common three-dimensional structure", and claims 7 and 11 recite a "branched" compound. After extensive review, the Examiner is unable to find, in the Specification as originally filed, support for these newly added limitations in the claims. These newly added limitations are not expressly asserted, nor do they flow naturally from the Specification as originally filed. [Pp. 6-7; par. 25; emphasis in original.]

Applicants disagree, but respectfully submit that the amendments to claims 1 and 3 address these points, as the term "extracting" has been removed.

Claims 4-11 have been canceled and the rejections of these claims are rendered moot.

Applicants respectfully submit that the present amendments to claims 1 and 3 accommodate the Examiner's rejection of these claims under 35 U.S.C. §112, first paragraph, thereby placing these claims in condition for allowance.

#### **VIII. Additional Remarks by the Examiner**

The Examiner has also alleged that "a meaningful search of the scientific literature cannot be performed" with respect to the previous amendments to claims 1 and 3 (page 7, par. 27). While Applicants disagree, they have amended claims 1 and 3 and respectfully request examination of these claims accordingly.

The Examiner has also mentioned two U.S. patents made of record and not relied upon (U.S. Pat. 6,586,191 and U.S. Pat. 6,368,812):

- 1.) U.S. Pat. No. 6,586,191 B2 teaches methods of screening compounds which bind to a human galanin receptor using binding and competitive binding assays.
- 2.) U.S. Pat. No. 6,368,812 B1 teaches methods of screening compounds which bind to or activate a human galanin receptor via a second messenger functional assay. [P. 7; par. 28.]

Applicants thank the Examiner for noting these references.

#### **IX. Request for Filing Receipt**

Applicants have not yet received an Official Filing Receipt. Applicants have filed Requests for an Official Filing Receipt on September 21, 2004, and on February 8, 2005, but have not received a response. Applicants respectfully request any assistance the Examiner could provide in obtaining an Official Filing Receipt.

## X. Conclusion

It is believed that all outstanding rejections have been addressed by this submission and that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

Applicants believe that no extension of time is required for the Amendment and accompanying materials. If an extension of time is required, Applicants hereby request the Examiner to consider this a conditional petition for an extension of time. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

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